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 Varian Medical Systems, Inc.

UNITED STATES DISTRICT COURT  
 SOUTHERN DISTRICT OF NEW YORK

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	:
CHARLES JARVIS and KARON JARVIS,	07 CV 8181 ( <i>RMS</i> )
	:
Plaintiffs,	
	:
- against -	<b>VARIAN MEDICAL SYSTEMS,</b>
	<b>INC.'S ANSWER WITH</b>
	<b>AFFIRMATIVE DEFENSES</b>
VARIAN MEDICAL SYSTEMS, INC.,	
	<b>JURY DEMAND</b>
Defendant.	
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Defendant Varian Medical Systems, Inc. ("Varian"), by and through its attorneys, Patterson Belknap Webb & Tyler LLP, answers plaintiffs' verified complaint ("complaint") as follows:

1. Varian denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the complaint and, therefore, denies the same.

**AS TO THE FIRST CAUSE OF ACTION**

2. Varian denies each and every allegation and legal conclusion asserted in paragraphs 2 and 3 of the complaint except admits that Varian is a Delaware corporation with its principal place of business in Palo Alto, California.

3. Varian denies each and every allegation and legal conclusion asserted in paragraphs 4 through 6 of the complaint except admits that Varian manufactures and distributes radiation oncology products, including the Clinac® 21 EX linear accelerator.

4. Varian denies each and every allegation and legal conclusion asserted in paragraphs 7 through 13 of the complaint.

AS TO THE SECOND CAUSE OF ACTION

5. With respect to paragraph 14 of the complaint, Varian repeats and realleges its answers to paragraphs 1 through 13 of the complaint with the same force and effect as if hereinafter set forth at length.

6. Varian denies each and every allegation and legal conclusion asserted in paragraphs 15 and 16 of the complaint except admits that Varian manufactures and distributes radiation oncology products, including the Clinac® 21 EX linear accelerator.

AS TO THE THIRD CAUSE OF ACTION

7. With respect to paragraph 17 of the complaint, Varian repeats and realleges its answers to paragraphs 1 through 16 of the complaint with the same force and effect as if hereinafter set forth at length.

8. Varian denies each and every allegation and legal conclusion asserted in paragraphs 18 and 19 of the complaint except admits that Varian manufactures and distributes radiation oncology products, including the Clinac® 21 EX linear accelerator.

AS TO THE FOURTH CAUSE OF ACTION

9. With respect to paragraph 20 of the complaint, Varian repeats and realleges its answers to paragraphs 1 through 19 of the complaint with the same force and effect as if hereinafter set forth at length.

10. Varian denies each and every allegation and legal conclusion asserted in paragraphs 21 through 25 of the complaint except admits that Varian manufactures and distributes radiation oncology products, including the Clinac® 21 EX linear accelerator.

**AS TO THE FIFTH CAUSE OF ACTION**

11. With respect to paragraph 26 of the complaint, Varian repeats and realleges its answers to paragraphs 1 through 25 of the complaint with the same force and effect as if hereinafter set forth at length.

12. Varian denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 27 of the complaint and, therefore, denies the same.

13. Varian denies each and every allegation and legal conclusion asserted in paragraphs 27 and 28 of the complaint.

**DEMAND FOR JUDGMENT**

Varian controverts plaintiffs' Demand for Judgment.

**AFFIRMATIVE DEFENSES**

**First Affirmative Defense**

The complaint and each cause of action therein fail to state a claim upon which relief may be granted against Varian.

**Second Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations.

**Third Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of laches, waiver, and estoppel.

**Fourth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by plaintiffs' comparative negligence.

**Fifth Affirmative Defense**

Plaintiffs knowingly, intentionally and voluntarily assumed any and all risks inherent in the use of the product and/or were contributorily negligent and/or engaged in misuse or abuse of said product, which conduct is a complete bar to plaintiffs' recovery, if any.

**Sixth Affirmative Defense**

Whatever injuries plaintiffs may have sustained were caused, in whole or in part, or were contributed to, by the culpable conduct and/or want of care on the part of the plaintiffs or by someone over whom Varian had no control.

**Seventh Affirmative Defense**

If plaintiffs sustained any of the injuries alleged in the complaint, which is denied, there was an intervening cause and/or causes leading to said alleged injuries, and as such, any action on the part of Varian was not the proximate and/or competent producing cause of plaintiffs' alleged injuries.

**Eighth Affirmative Defense**

If plaintiffs sustained any of the injuries alleged in the complaint, which is denied, said injuries were caused in full or in part by the conduct of one or more third persons for whose conduct Varian is not responsible or with whom Varian has no legal relation, and the independent knowledge and awareness of such other persons or entities of the risks inherent in

the use of the product in question and other independent causes, such as pre-existing or co-existing medical conditions, constitutes an intervening and superseding cause of plaintiffs' alleged damages.

**Ninth Affirmative Defense**

Varian is entitled to the benefit of all defenses and presumptions which may arise because the design, manufacture, inspection, packaging, issuing of warnings and instructions and/or labeling of the product, which is the subject of the complaint, were in conformity with the generally recognized, reasonably available and reliable scientific, medical, and technological state-of-the-art and prevailing standards in the industry at the time the product was manufactured.

**Tenth Affirmative Defense**

Plaintiffs' alleged injuries, if any, were caused, in whole or in part, by pre-existing conditions.

**Eleventh Affirmative Defense**

At all relevant times, Varian presumptively exercised due care and its products and its warnings and instructions were governed by and conformed with applicable federal statutes, rules and regulations; therefore, the Varian product (if involved herein, which is denied) was presumptively not defective and the warnings and instructions relating to its product were presumptively adequate.

**Twelfth Affirmative Defense**

If Varian's product was involved in the injuries claimed by plaintiffs, which is denied, upon information and belief, the use of the product was improper and not in accordance

with prescribed, correct procedures. Accordingly, the product was abused, misused and applied for purposes other than those that were indicated or intended by Varian.

**Thirteenth Affirmative Defense**

Varian did not make to plaintiffs nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred based on plaintiffs' lack of privity with Varian and, additionally, because there was no reliance upon any warranties of Varian and/or for failure of plaintiffs, or plaintiffs' representatives, to give timely notice to Varian of any alleged breach of warranty. Varian further specifically pleads as to any breach of warranty claim all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future.

**Fourteenth Affirmative Defense**

Any and all warranties relating to the product allegedly at issue have been disclaimed.

**Fifteenth Affirmative Defense**

Varian provided adequate and complete warnings and instructions to plaintiffs prescribing physicians. Therefore, any claims by plaintiffs for inadequate warnings and/or instructions are controlled by and barred under the learned intermediary doctrine.

**Sixteenth Affirmative Defense**

Plaintiffs' claims are barred in whole or in part under comment j and comment k of Section 402 A of the Restatement (Second) of Torts and Section 6, et seq. of the Restatement (Third) of Torts: Products Liability.

**Seventeenth Affirmative Defense**

Plaintiffs' claims are barred by informed consent, release and waiver.

**Eighteenth Affirmative Defense**

Plaintiffs' claims are preempted by the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act and the United States Food and Drug Administration ("FDA") regulations promulgated pursuant thereto.

**Nineteenth Affirmative Defense**

Plaintiffs' claims are preempted, in whole or in part, by federal law under the Supremacy Clause of the United States Constitution.

**Twentieth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because FDA has exclusive or primary jurisdiction over the matters asserted in the complaint.

**Twenty-First Affirmative Defense**

Any claims by plaintiffs related to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government and *Bucbnan v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001).

**Twenty-Second Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because any alleged representations with respect to the product were not false or misleading and constitute protected speech under the applicable provisions of the United States Constitution, including the First Amendment.

**Twenty-Third Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, because the utility of the product in question was consistent with and/or exceeded consumer expectations, and because the benefits of the product, as marketed and sold, outweighed its risks.

**Twenty-Fourth Affirmative Defense**

Plaintiffs' recovery, if any, must be reduced by any amount of damages legally caused by Plaintiffs' failure to mitigate such damages in whole or in part.

**Twenty-Fifth Affirmative Defense**

Plaintiffs' complaint and each cause of action therein fail to name a necessary and indispensable party.

**Twenty-Sixth Affirmative Defense**

Plaintiffs' alleged damages, if any and if caused by the product in question, were caused in whole or in part by changes and/or alterations to the product in question made by persons not within Varian's control.

**Twenty-Seventh Affirmative Defense**

Plaintiffs' claims are barred in whole or in part by the learned intermediary, informed intermediary, and/or sophisticated user doctrines.

**Twenty-Eighth Affirmative Defense**

Varian is entitled to a set-off for the total of all amounts paid to plaintiffs from any and all collateral sources.

**Twenty-Ninth Affirmative Defense**

Plaintiffs' claims are barred, in whole or in part, by their failure to assert a safer, economically feasible alternative design for the product in question.



**Thirtieth Affirmative Defense**

Plaintiffs' recovery, if any, must be diminished in proportion to any culpable conduct in accordance with C.P.L.R. § 1411.

**Thirty-First Affirmative Defense**

Pursuant to C.P.L.R. §§ 1601 and 1602, although Varian denies that it is liable herein, to the extent Varian is held liable to plaintiffs, its share of the damages should be limited in accordance with any relative culpability.

**Thirty-Second Affirmative Defense**

Plaintiffs' claims for the cost of medical care, rehabilitation services, loss of earnings or other economic loss are subject to the provisions of C.P.L.R. § 4545 and any such past or future costs or expenses which were or will be replaced or indemnified, in whole or in part, from any collateral source are not recoverable in this action.

**Thirty-Third Affirmative Defense**

To the extent plaintiffs have or will settle with any other person with respect to the allegations in the complaint, the liability of Varian, if any, shall be reduced pursuant to section 15-108 of the General Obligations Law.

**Thirty-Fourth Affirmative Defense**

Plaintiffs' complaint fails to allege a claim for which punitive damages can be recovered.

**Thirty-Fifth Affirmative Defense**

No act or alleged omission by Varian was malicious, willful, wanton, reckless, or grossly negligent; therefore, any award of punitive damages is barred.

**Thirty-Sixth Affirmative Defense**

Plaintiffs' complaint fails to allege facts which meet the clear and convincing standards of proof required for the recovery of punitive damages.

**Thirty-Seventh Affirmative Defense**

With respect to plaintiffs' claim for punitive damages, Varian specifically incorporates by reference all standards or limitations regarding the determination, amount, and enforceability of punitive damages awards set forth in *BMW of North America v. Gore*, 116 U.S. 1589 (1996) and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

**Thirty-Eighth Affirmative Defense**

If plaintiffs sustained damages as alleged in the complaint, which Varian denies, the assessment of punitive damages violates Varian's constitutional rights under the Fifth, Sixth, Eighth and Fourteenth Amendments of the United States Constitution, in one or more of the following respects:

- (a) The guidelines, standards, and/or instructions for assessing punitive damages are vague, indefinite, and/or uncertain, supply no notice to Varian of the potential repercussions of its alleged conduct, set no limit on the damages that can be awarded, fail to require proof of every element beyond a reasonable doubt, are subject to the unbridled discretion of the jury, and do not allow adequate judicial review, thereby denying due process;
- (b) The assessment of punitive damages is criminal or penal in nature and, therefore, the rights given defendants in criminal proceedings are applicable;
- (c) The assessment of punitive damages amounts to the imposition of an excessive fine and/or cruel and unusual punishment;
- (d) The assessment of punitive damages exposes Varian to multiple punishments and fines for the same act;
- (e) The assessment of punitive damages constitutes double jeopardy;

- (f) The assessment of punitive damages discriminates against Varian in that Varian's corporate status, wealth, or net worth may be considered by the jury in determining the amounts of any such damage awards and different amounts can be awarded against different defendants for the same act depending solely on the status or material wealth of the various defendants, thereby denying equal protection under the law;
- (g) The assessment of punitive damages does not provide an adequate procedure for the determination of punitive damages in violation of the equal protection and substantive and procedural due process requirements of the United States Constitution and in violation of the United States Supreme Court's decision in *Pacific Mutual Ins. Co. v. Haslip*;
- (h) The assessment of punitive damages constitutes an impermissible burden on interstate commerce; and
- (i) The assessment of punitive damages constitutes a violation of due process and other constitutional rights of Varian as set forth in the United States Supreme Court decision in *State Farm Mut. Auto. Ins. Co. v. Campbell*.

**Thirty-Ninth Affirmative Defense**


Varian hereby gives notice that it intends to rely on such other affirmative defenses as may become available or apparent during the course of discovery and reserve the right to amend their answer to assert any such defense.

WHEREFORE, Defendant Varian Medical Systems, Inc. requests that an Order be entered dismissing plaintiffs' Verified Complaint with prejudice and awarding Varian such other relief as it deems just.

Dated: New York, New York  
September 25, 2007

PATTERSON BE&KNAP WEBB & TYLER LLP

By: \_\_\_\_\_

  
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**DEMAND FOR JURY TRIAL**

Defendant Varian Medical Systems, Inc. respectfully requests trial by jury with the maximum number of jurors provided by law.

Dated: New York, New York  
September 25, 2007

PATTERSON BAKNAP WEBB & TYLER LLP

By: \_\_\_\_\_

*John D. Winter*

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